CLAIMS:

1. A gastro-retentive diagnostic assembly (GRDA) for use in determining a condition of a subject's GI tract, comprising a folded single or multi-layered device comprising a diagnostic utility, the device prior to folding being essentially planar, and included in a delivery system for oral intake, the delivery system being adapted to release the device once in said subject's stomach, whereupon release said device unfolds into an unfolded shape that results in the retention of the device in the stomach.

2. The GRDA of Claim 1, wherein said diagnostic utility comprises a contrasting agent.

3. The GRDA of claim 2, wherein the contrasting agent is a contrasting agent for X-ray, ultrasound, γ-scintigraphy or MRI imaging.

4. The GRDA of claim 2, wherein said contrasting agent is retained in the device once unfolded for a period of time permitting imaging of the stomach.

5. The GRDA of claim 4, wherein the contrasting agent is released from the device at a rate so as to permit imaging of the device throughout a substantial portion of time of the device's retention in the stomach.

6. The GRDA of claim 1, wherein the delivery system is selected from a capsule containing the folded device, a tube surrounding the folded device, a polymeric coating, a polymer or gel matrix embedding the folded device.

7. The GRDA of claim 1, wherein the device comprises a single layer comprising said diagnostic utility.

8. The GRDA of Claim 7, wherein said diagnostic utility is adsorbed onto, or embedded in said single layer or is absorbed into a carrier that is attached to said single layer.

9. The GRDA of Claim 1, wherein the device comprises two layers sandwiching said contrasting agent between them.

10. The GRDA of claim 1, wherein said single or multi-layered device comprises a matrix, and said diagnostic utility is adsorbed to, embedded in or sandwiched between matrix layers, or is absorbed into a carrier that is attached to the layers, or any combination thereof.

11. The GRDA of any one of the preceding claims, wherein said device comprises a polymeric composition for maintaining a configuration of the device when unfolded that provides for said retention of the device in the stomach.

12. The GRDA of Claim 10 and 11, wherein said polymeric composition is attached to said matrix or is integrally formed therewith.

13. The GRDA of any one of the preceding claims, where the device unfolds into a generally planar configuration.

14. The GRDA of any one of the preceding claims, wherein the folding to yield said folded device is by one or more of folding about fold lines, rolling, bending twisting, winding or crimping.

15. The GRDA of any one of Claims 2 to 14, wherein said contrasting agent is one or more of: gadolinium, manganese or iron based low molecular weight compounds, dia- or super- paramagnetic iron oxides, perfluorocarbons, radioactive isotopes or radiolabled organic compounds.

16. The GRDA of Claim 15, wherein said contrasting agent is a superparamagnetic iron oxide (SPIO).

17. The GRDA of any one of the preceding claims, wherein said diagnostic utility is associated with a vector for delivery of the diagnostic utility to the stomach's lumen, the diagnostic utility associated with the vector being releasable from the device when the device is in an unfolded state.

18. The GRDA of Claim 17, wherein said vector molecule is a small molecular weight molecule, a peptide, a protein, a polysaccharide, a liposome or a cell.

19. The GRDA of Claim 1, wherein said device is folded in an accordion-like or fan-like configuration.

20. The GRDA of any one of the preceding Claims, wherein said delivery system is a hard gelatin capsule.

21. The GRDA of any one of the preceding Claims, wherein when in an unfolded state, said device has an essentially oval shape.

22. The GRDA of Claim 21, wherein said device is 45 mm long by 24 mm wide.

23. A method of determining a condition of a subject's GI tract comprising:

administering to a subject with a GRDA comprising a folded single or multi-layered device comprising a diagnostic utility, the device prior to folding being essentially planar, and being included within a delivery system for oral intake, the delivery system adapted to release the device once in the subject's stomach, whereupon release, said device unfolds into an unfolded shape that results in the retention of the device in the stomach; and

retrieving data indicative of a condition of the subject's GI tract.

24. The method of Claim 23, wherein said diagnostic utility comprises a contrasting agent.

25. The method of Claim 24, comprising imaging of said subject's GI tract.

26. The method of Claim 25, wherein said imaging of the GI tract comprises X-ray, ultrasound, γ-scintigraphy or MRI imaging.

27. The method of any one of Claims 24 to 26, wherein said contrasting agent is one or more of: gadolinium, manganese or iron based low molecular weight

compounds, dia- or super- paramagnetic iron oxides, perfluorocarbons, radioactive isotopes or radiolabled organic compounds.

28. The method of Claim 27, wherein said contrasting agent is a superparamagnetic iron oxide (SPIO).

29. The method of any one of Claims 24 to 28, wherein said contrasting agent is retained in the device once unfolded for a period of time permitting imaging of the GI tract.

30. The method of any one of Claims 24 to 28, wherein the contrasting agent is released from the device at a rate so as to permit imaging of the device throughout a substantial portion of time of the device's retention in the stomach.

31. The method of any one of Claims 23 to 30, wherein the device comprises a single layer comprising said diagnostic utility adsorbed onto, embedded in said single layer or absorbed into a carrier attached to the device.

32. The method of any one of Claims 23 to 30, wherein the device comprises two layers sandwiching said diagnostic utility between them.

33. The method of any one of Claims 23 to 32, wherein said single or multi-layered device comprises is a matrix and said diagnostic utility is adsorbed to, embedded in or sandwiched between the layers.

34. The method of any one of Claims 23 to 33, wherein upon delivery to the subject said device is folded in an accordion-like or fan-like configuration in said delivery system.

35. The method of any one of Claims 23 to 34, wherein said delivery system is a hard gelatin capsule.

36. The method of any one of Claims 23 to 35, wherein said data indicative of said condition of the GI tract is retrieved when the single or multi-layered device is in a generally planar shape.

37. The method of any one of Claims 23 to 36, wherein said data is retrieved within a time window of at least 48 hours post administration of the GRDA to the subject.

38. The method of Claim 37, wherein said time window is of at least 18 hours post administration.

39. The method of Claim 37, wherein said time window is of at least 10 hours post administration.

40. The method of Claim 37, wherein said time window is of at least 5 hours post administration.

41. The method of any one of Claims 37 to 40, wherein said diagnostic utility comprises a contrasting agent and said method comprises capturing one or more images during said time window.

42. The method of any one of Claims 23 to 41, for determining a pathological condition in a subject's GI tract.

43. The method of Claim 42, wherein said pathological condition is a condition of the stomach.

44. The method of Claim 42, wherein said condition is a condition of the stomach selected from gastroparesis, gastritis, gastroenteritis, gastric ulcer and gastric cancer

45. The method of Claim 42, wherein said pathological condition is selected from irritable bowel syndrome, GI bleeding, GI portal hypertension, colitis, diverticulosis, colon polyps, GI cancer, carcinoid, inflammatory bowel disease (IBD), GI obstructions and metabolic diseases associated with excess or deficient secretion of gut hormones.

46. The method of any one of Claims 23 to 45, for monitoring a change in a pathological condition in a subject's GI tract.

47. The method of Claim 46, comprising sequential administrations of a GRDA to a subject, each administration followed by retrieval of data indicative of the condition of the subject's GI tract.

48. Use of a generally planar single or multi-layered device comprising a diagnostic utility for the preparation of a GRDA for oral intake, the GRDA comprising said device in a folded configuration and included in a delivery system, the delivery system being adapted to release the single or multi-layered device once in the stomach whereupon release, said device unfolds into an unfolded shape that results in the retention of the device in the stomach.

49. The use of Claim 48, wherein said GRDA is as defined in any one of Claims 1 to 20.

50. The use of Claim 48 or 49, wherein said GRDA is for determining a pathological condition in a subject's GI tract or for monitoring a change in a pathological condition in a subject's GI tract during or after providing said subject with a treatment for said pathological condition.

51. A method for preparing a GRDA for use in determining a condition of a subject's GI tract, the method comprises: (i) providing an unfolded and essentially planar single or multi-layered device comprising a diagnostic utility; (ii) folding said device; and (iii) introducing or combining the folded device with a delivery system, such that when in the stomach it is released from the delivery system, whereupon release it unfolds into an unfolded shape that results in the retention of the device in the stomach.

52. The method of Claim 51, for the preparation of a GRDA as defined in any one of Claims 1 to 22.